UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

08/900559

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.

EXAMINER	
ART UNIT	PAPER NUMBER
	7

DATE MAILED:

INTERVIEW SUMMARY

All participants (applicant, applicant's representative, PTO personnel):

(1) Vicki G. Newton, Reg. No. 40,745 (3) _____

(2) Carol A. Spiegel (4) _____

Date of Interview 10/27/98

Type: ☐ Telephonic ☐ Personal (copy is given to ☐ applicant ☐ applicant's representative).

Exhibit shown or demonstration conducted: ☒ Yes ☐ No If yes, brief description: FAXED Draft Amended Claims

Agreement ☐ was reached. ☒ was not reached.

Claim(s) discussed: draft claims

Identification of prior art discussed: Amrich

Description of the general nature of what was agreed to if an agreement was reached, or any other comments: ① discussed counter proposal to draft claims ② emphasized separateness of the device and the assay chamber as two distinct physical entities ③ Amrich would change to an obviousness rejection if draft claims made of record to replace pending claims ④ discussed requirements/issues raised with a Rule 132 affidavit of commercial success

(A fuller description, if necessary, and a copy of the amendments, if available, which the examiner agreed would render the claims allowable must be attached. Also, where no copy of the amendments which would render the claims allowable is available, a summary thereof must be attached.)

1. ☒ It is not necessary for applicant to provide a separate record of the substance of the interview.

Unless the paragraph above has been checked to indicate to the contrary. A FORMAL WRITTEN RESPONSE TO THE LAST OFFICE ACTION IS NOT WAIVED AND MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a response to the last Office action has are ready been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW.

2. ☐ Since the Examiner's interview summary above (including any attachments) reflects a complete response to each of the objections, rejections and requirements that may be present in the last Office action, and since the claims are now allowable, this completed form is considered to fulfill the response requirements of the last Office action. Applicant is not relieved from providing a separate record of the interview unless box 1 above is also checked.

Examiner Note: You must sign this form unless it is an attachment to another form Carol A. Spiegel 10/27/98

FORM PTOL-413 (REV.1-96)

attachment to paper # 7.

LYON & LYON LLP
A LIMITED LIABILITY PARTNERSHIP
INCLUDING PROFESSIONAL CORPORATIONS
4225 Executive Square, Suite 800
La Jolla, California 92037
Phone: (619) 552-8400
Fax: (619) 552-0159

FACSIMILE TRANSMITTAL FORM

To:	Fax Number:	Phone Number:
Examiner Carol A. Spiegel	(703) 308-4426 (703)308-4242	(703) 308-3986
From:	**Fax Number:**	**Phone Number:**
Vicki G. Norton	(619) 552-0159	(619) 552-8400
Re:	**Date/Time sent:**	**No. of Pages:**
08/900,559	10/15/98 5:24 AM	(incl. cover)
Client Name:	**Client Matter No.:**	

If you do not receive all of the pages, please call Debbie Higa at (619) 552-8400, extension 5595.

Notes/Comments:

Examiner Spiegel—As we discussed a few weeks ago, I am sending you proposed amended claims for Application Serial Number 08/900,559.

TO BE COMPLETED BY FAX OPERATOR

TIME TRANSMITTED: _____ TRANSMITTED BY: _____

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of:

Cheng et al.

Serial No.: 08/900,559

Filed: 07/25/97

For: METHOD OF USE OF ONE STEP IMMUNOCHROMATOGRAPHIC DEVICE FOR STREPTOCOCCUS A ANTIGEN

Group Art Unit: 1641

Examiner: Carol A. Spiegel

DRAFT AMENDED CLAIMS

Examiner Spiegel:

Attached are proposed amended claims for the above-referenced application. I would like to call you on October 16, 1998 or another time more convenient for you, in order to discuss the proposed amendments.

Kindly cancel claims 1-9 and add the following claims 10-20:

10. A method for determining the presence or absence of Streptococcus Group A antigen in a sample, comprising:

(a) providing a lateral flow immunochromatographic device comprising a sample receiving region of porous material in liquid flow contact with a separate detection region of porous material,
wherein said detection region comprises a mobile labeling reagent at a discrete labeling situs and an immobilized capture reagent at a discrete capture situs, and
wherein said labeling reagent is a detectable label coupled to a binder which specifically binds to said antigen to form a labeled complex and said capture reagent specifically binds to said antigen or to said labeled complex;

(b) extracting said antigen from said sample with an extraction solution comprising one or two extraction reagents in an assay chamber, wherein said one extraction reagent is added to the assay chamber, to form a liquid extract, or wherein said two extraction reagents are added to said assay chamber in any order, to form a liquid extract;

NB assay Chamber defined p2 ln 1

(c) inserting said sample receiving region of said lateral flow immunochromatographic device into said liquid extract whereby said liquid extract flows through said labeling situs and then through said capture situs, without further addition of reagents or manipulation of said sample; and

(d) determining the presence or absence of said antigen in said sample by detecting the presence or absence of said detectable label at said capture situs.

11. The method of claim 10 wherein said detection region further comprises both a discrete control labeling situs comprising a ~~liquid mobilizable~~ labeled control reagent and a discrete control capture situs comprising an immobilized control capture reagent which specifically binds to and immobilizes said labeled control reagent, and wherein said method further comprises

(e) determining the presence of said immobilized labeled control reagent at said control capture situs as an internal control that the assay was performed properly.

12. The method of claim 10 wherein said sample is a throat swab sample and said extracting step further comprises contacting said throat swab sample with said extraction solution for at least 10 seconds.

13. The method of claim 12 wherein said sample is a throat swab sample and said extracting step further comprises vigorously mixing said throat swab in said extraction solution for at least 10 seconds.

14. The method of claim 10 wherein said extraction solution comprises 0.1-2.5 M sodium nitrite and 0.01-1 M acetic acid.

15. The method of claim 10 wherein said two extraction reagents comprise a 0.2-5 M sodium nitrite solution and a 0.02-2 M acetic acid solution.

16. The method of claim 14 wherein the sodium nitrite solution comprises 2 M sodium nitrite and a pH color indicator reagent and the acetic acid solution has a concentration of 0.3 M, wherein the 0.3 M acetic acid solution is added to the 2 M sodium nitrite solution, and wherein said pH color indicator reagent changes color as the 0.3 M acetic acid solution is added to the 2 M sodium nitrite solution.

17. The method of claim 10 wherein said sample receiving region further comprises a buffer which neutralizes said liquid extract.

18. The method of claim 10 wherein one lateral flow immunochromatographic device is laminated to a backing support strip and the remaining side is not covered.

19. The method of claim 10 wherein one lateral flow side of said lateral flow immunochromatographic device is laminated to a backing support strip and the remaining side is partially covered with a strip of plastic material which allows the capture situs to be visible ~~and~~ so as to leave a portion of said sample receiving region exposed for ~~contacting~~ insertion into said liquid extract.

20. A method for ~~determining~~ the presence or absence of Streptococcus antigen in a sample, comprising:

(a) providing a lateral flow immunochromatographic device comprising a sample receiving region of porous material in liquid flow contact with a separate detection region of porous material, wherein said detection region comprises a ~~liquid mobilizable~~ labeling reagent at a discrete labeling situs and an immobilized capture reagent at a discrete capture situs; and
wherein said labeling reagent is a detectable label coupled to a binder which specifically binds to said antigen to form a labeled complex and said capture reagent to a binder which specifically binds to said antigen or to said labeled complex;

(b) extracting said antigen from said sample with a liquid extraction solution comprising one or two extraction reagents in an assay chamber, wherein said one extraction reagent is added to the assay chamber, to form a liquid extract, or wherein said two extraction reagents are added to said assay chamber in any order, to form a liquid extract;

(c) inserting said sample receiving region into said liquid extract whereby said liquid extract flows through said labeling situs and then through said capture situs without further addition of reagents or manipulation of said sample; and

(d) determining the presence or absence of said antigen in said sample by detecting the presence or absence of said detectable label at said capture situs.

Claims 10-13, and 15-20 correspond substantially to the Examiner's proposed Claims 1-9.

Applicants have further clarified step (c) of claims 10 and 20 to more clearly state that the immunodiagnostic device is inserted into the liquid extract sample following the extraction step. Spatial separation of the assay chamber from lateral flow contact with the sample receiving region of the lateral flow immunochromatographic assay device permits greater control over the length and efficiency of extraction, and the sensitivity of the assay.

1) inserting into said assay chamber such that said liquid extract
2) providing an assay chamber to point out clearly that device & chamber are separate elements